

REMARKS

Applicant respectfully requests reconsideration. Claims 1-5, 25 and 28-38 are pending in this application. Claims 1-5 and 37-38 were previously withdrawn from consideration. Claim 25 has been amended. As a result, claims 25 and 28-36 are pending for examination with claim 25 being the sole independent claim and no new matter has been added.

Rejections Under 35 U.S.C. §102

Claims 25 and 28-35 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,384,239 (Saunders et al.).

Applicant respectfully disagrees. However, Applicant has amended claim 25 to recite:

A method for obtaining information about the blood glucose level history of a patient, the method comprising the steps of:

- (a) obtaining a blood sample comprising a plurality of intact red blood cells;
- (b) sorting the plurality of intact red blood cells as a function of a detected amount of glycated hemoglobin for each cell and generating a cell distribution profile that represents the number of red blood cells as a function of the amount of glycated hemoglobin per cell; and,
- (c) dividing the cell distribution profile into a series of bins each containing a number of cells representing a time interval and calculating a change in the amount of glycated hemoglobin for each bin, thereby obtaining information about the blood glucose level history of the patient for each time interval represented by the series of bins, wherein both the time interval and the blood glucose level are determined based on the detected amount of glycated hemoglobin.

Applicant respectfully submits that Saunders et al. fails to teach a method that involves determining both a time interval and the blood glucose level for that time interval based on detected amounts of glycated hemoglobin. In contrast, Saunders et al. teaches using a separate technique to evaluate the age of a cell sample in order to determine the amount of glycated hemoglobin that is associated with a particular age of cell. For example, column 3, lines 7-10, teaches that “[i]n a preferred embodiment, red blood cells from a single sample are separated according to age into a plurality of age cohorts, e.g., by capillary centrifugation.” Column 4, lines 13-14, teaches that “[r]ed blood cells (RBCs) may be fractionated according to age by density gradient methods.” Column 4, lines 19-21 teaches that “[p]hysical separation of the red blood cells is not required if cells of different ages can otherwise be distinguished.” However, Saunders et al. fails to even suggest, let alone teach, methods that use a detected amount of glycated hemoglobin in intact red

blood cells to determine both a time interval and a glucose level in a patient during that time interval.

Accordingly, reconsideration and withdrawal of the rejection of claim 25, and dependent claims 28-35, under 35 U.S.C. §102 is respectfully requested.

Rejections Under 35 U.S.C. §103

Claims 25 and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,384,239 (Saunders et al.), as applied to claim 25 above, in view of U.S. Publication No. 20040214243 (Burshteyn et al.).

Applicant respectfully submits that Burshteyn et al. also fails to suggest or teach methods that use a detected amount of glycated hemoglobin in intact red blood cells to determine both a time interval and a glucose level in a patient during that time interval. Therefore, Saunders et al. in view of Burshteyn et al. cannot form the basis for a continued rejection of either claim 25 or dependent claim 36 under 35 U.S.C. §103(a).

Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103 is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

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Respectfully submitted,

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